I. Office Action

As an initial matter, Applicants would like to thank Examiner Jastrzab for allowing and conducting the telephone interview of October 13, 2005. In the interview, Applicants inquired as to why the time period for response to the September 22, 2005, Office Action had been set at one month. In response, Examiner Jastrzab informed Applicants that, rather than being set at one month, the time period of response to the Office Action should have been set at three months. Applicants thank the Examiner for correcting the time period for response and issuing the Interview Summary of October 17, 2005.

In the Office Action mailed on September 22, 2005, the Examiner rejected claims 66-79 under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter, indicated that claims 15-65 are allowable, and indicated that claims 66-79 would be allowable if amended to overcome the Examiner's rejection under 35 U.S.C. § 101. The Examiner also indicated that the Terminal Disclaimer filed on January 24, 2003 was accepted and recorded. Lastly, the Examiner also required Applicants to file a Suggestion for Interference under Rule 41.202. This filing responds to that request.

With respect to the Examiner's rejection of claims 66-79 under 35 U.S.C. § 101, Applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution of the present application, Applicants have amended claim 66 to recite that the device comprises "a structure having a first and a second portion, said structure adapted to encircle the natural heart and to exert a constant inward displacement on at least two discrete portions of the exterior surface of one and only one chamber of the

natural heart," thereby rendering the Examiner's rejection moot. Accordingly, claim 66 and its dependents satisfy the requirements of 35 U.S.C. § 101 and are therefore allowable.

II. Suggestion Under 37 C.F.R. § 41.202 for an Interference With U.S. Patent Nos. 6,190,408 and 6,409,760

In the Preliminary Amendment filed on February 14, 2002, Applicants presented claims 15-39 for the purposes of interference between this application and the '408 patent. In the Amendment filed on January 24, 2003, Applicants presented claims 40-79 for the purposes of interference between this application and the '760 patent.

As Applicants will demonstrate, claims 15-39 of the present application define allowable subject matter that interferes with the claims in the '408 patent, and claims 40-79 of the present application define allowable subject matter that interferes with the claims in the '760 patent. Accordingly, Applicants request that an interference be declared between claims 15-39 of this application and claims 1-24 and 31-39 of the '408 patent, and between claims 40-79 of this application and claims 1-50 of the '760 patent.

A. Identification of Patents With Which Applicants Seek an Interference

Applicants seek an interference with U.S. Patent Nos. 6,190,408 and 6,409,760. See 37 C.F.R. § 41.202(a)(1). The '760 patent was filed as a continuation application of the application that became the '408 patent. The '760 and '408 patents have identical disclosure and name the same sole inventor, David Melvin.

B. An Interference Between the Present Application and the '408 and '760 Patents is Appropriate

An interference is appropriate between an application and an unexpired patent of different parties if the subject matter of one party would, if prior art, have anticipated or

rendered obvious the subject matter of a claim of the opposing party and vice versa. 37 C.F.R. § 41.203(a). In other words, an interference is appropriate when the application and patent contain claims to the same patentable invention. The Board uses a two-way test to determine patentability. *See Eli Lilly & Co. v. Board of Regents of the University of Washington,* 334 F.3d 1264 (Fed. Cir. 2003).

1. Claims 15-39 of the Present Application and the '408 Patent Claims Define the Same Patentable Invention

The two-way test is satisfied here at least because the present application and the '408 patent share identical claims. For example, because application claim 15 is identical to claim 1 of the '408 patent, Applicants' claimed subject matter defined by application claim 15 fully anticipates the claimed subject matter of the '408 patent defined by claim 1. Analogously, the claimed subject matter of the '408 patent defined by claim 1 fully anticipates Applicants' claimed subject matter defined by claim 15. Thus, the claimed subject matter of the '408 patent is the same as the claimed subject matter of this application and vice versa. Accordingly, the two-way test for patentability is satisfied in this case.

The two-way test is also satisfied for other pending claims (16-39) of the present application that copy claims of the '408 patent. Specifically, claims 15, 19, 20, 21, 23, 24, and 34 are identical to claims 1, 3, 4, 5, 6, 7, and 34 of the '408 patent, respectively, and claims 16-18, 22, 25-33, and 35-39 include similar subject matter as at least claims 2, 5, 8, 9, 13-18, and 35-39 of the '408 patent. The substantial overlap between these claims clearly shows that the claimed subject matter of the '408 patent anticipates or renders obvious the claimed subject matter of this application and vice versa. Accordingly, the two-way test for patentability is satisfied in this case.

a. Proposed Counts

Applicants propose the following counts pursuant to 37 C.F.R. § 41.202(a)(2):

Count 1:

> A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising:
>
> a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and
>
> a connector joining the members, and said connector comprises a band configured for extending around the chamber and joining at least two of the members,
>
> wherein said members are fixed in a spaced relationship relative to each other such that at least two portions of the outer wall are displaced inwardly from the unrestricted position.

Count 2:

> A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising:
>
> a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and
>
> a first connector joining the members, the first connector having portions configured to be encased in the tissue of the heart,
>
> wherein said members are fixed in a spaced relationship relative to each other such that at least two portions of the outer wall are displaced inwardly from the unrestricted position.

Proposed Counts 1 and 2 incorporate the exact language of claims 15 and 34 of the present application and claims 1 and 34 of the '408 patent, respectively.

b. Claims Corresponding to the Proposed Counts

A claim should be designated as corresponding to the count if, considering the count as prior art, the claim would be unpatentable over the count under 35 U.S.C. § 102 or § 103. 37 C.F.R. § 41.207(b)(2).

In this case, assuming that Proposed Count 1 as recited above was prior art, claims 15-33 of this application and claims 1-24, 31-33, and 38-39 of the '408 patent would be unpatentable over Proposed Count 1 because these claims would be either anticipated by or rendered obvious by the subject matter of Proposed Count 1. For example, as shown in the claim chart in Section B(II)(a)(iii) below, claim 15 of the present application and claim 1 of the '408 patent are identical to Proposed Count 1. Therefore, claims 15-33 of this application and claims 1-24, 31-33, and 38-39 of the '408 patent correspond to Proposed Count 1.

Assuming that Proposed Count 2 as recited above was prior art, claims 34-39 of this application and claims 34-37 of the '408 patent would be unpatentable over Proposed Count 2 because these claims would be either anticipated by or rendered obvious by the subject matter of Proposed Count 2. For example, as shown in the claim chart in Section B(II)(a)(iii) below, claim 34 of the present application and claim 34 of the '408 patent are identical to Proposed Count 2. Therefore, claims 34-39 of this application and claims 34-37 of the '408 patent correspond to Proposed Count 2.

c. Claim Chart Comparing Interfering Subject Matter

37 C.F.R. § 41.202(a)(3) states: "For each count, provide a claim chart comparing at least one claim of each party corresponding to the count and show why the claims interfere within the meaning of § 41.203(a)."

As shown below, claim 15 of the present application and claim 1 of the '408 patent are identical to Proposed Count 1, and therefore interfere within the meaning of § 41.203(a).

Proposed Count 1	Claim 15 of Present Application	Claim 1 of the '408 Patent
A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and a connector joining the members, and said connector comprises a band configured for extending around the chamber and joining at least two of the members, wherein said members are fixed in a spaced relationship relative to each other such that at least two portions of the outer wall are displaced inwardly from the unrestricted position.	A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and a connector joining the members, and said connector comprises a band configured for extending around the chamber and joining at least two of the members, wherein said members are fixed in a spaced relationship relative to each other such that at least two portions of the outer wall are displaced inwardly from the unrestricted position.	A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and a connector joining the members, and said connector comprises a band configured for extending around the chamber and joining at least two of the members, wherein said members are fixed in a spaced relationship relative to each other such that at least two portions of the outer wall are displaced inwardly from the unrestricted position.

As shown below, claim 34 of the present application and claim 34 of the '408 patent are identical to Proposed Count 2, and therefore interfere with the meaning of § 41.203(a).

Proposed Count 2	Claim 34 of Present Application	Claim 34 of the '408 Patent
A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and a first connector joining the members, the first connector having portions configured to be encased in the tissue of the heart, wherein said members are fixed in a spaced relationship relative to each other such that at least two portions of the outer wall are displaced inwardly from the unrestricted position.	A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and a first connector joining the members, the first connector having portions configured to be encased in the tissue of the heart, wherein said members are fixed in a spaced relationship relative to each other such that at least two portions of the outer wall are displaced inwardly from the unrestricted position.	A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and a first connector joining the members, the first connector having portions configured to be encased in the tissue of the heart, wherein said members are fixed in a spaced relationship relative to each other such that at least two portions of the outer wall are displaced inwardly from the unrestricted position.

2. Claims 40-79 of the Present Application and the '760 Patent Claims Define the Same Patentable Invention

The two-way test is satisfied here at least because the present application and the '760 patent share identical claims. For example, because application claim 41 is identical to claim 2 of the '760 patent, Applicants' subject matter defined by claim 41 fully anticipates the subject matter of the '760 patent defined by claim 2. Analogously, the subject matter of the '760 patent defined by claim 2 fully anticipates Applicants' subject matter defined in claim 41. Thus, the claimed subject matter of the '760 patent

is the same as the claimed subject matter of this application and vice versa. Accordingly, the two-way test for patentability is satisfied.

The two-way test is also satisfied for other pending claims (40 and 42-79) of the present application that copy claims of the '760 patent. Specifically, claims 41, 42, 46-48, 50, 51, 63-65, 67-71, 73-75, and 77-79 are identical to claims 2, 3, 5-9, 28-30, 37-41, 43-45, and 47-50 of the '760 patent, respectively, and claims 40, 43-45, 49, 52-62, 66, 72, and 76 include similar subject matter as at least claims 1, 4, 7, 10, 11, 15-20, 24, 34-36, 42, and 46 of the '760 patent. The substantial overlap between these claims clearly shows that the claimed subject matter of the '760 patent anticipates or renders obvious the claimed subject matter of this application and vice versa. Accordingly, the two-way test for patentability is satisfied in this case.

a. Proposed Counts

Applicants propose the following counts pursuant to 37 C.F.R. § 41.202(a)(2):

Count 3:

> A static device for use with a heart having at least one chamber, said device comprising:
>
> a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and
>
> a connector joining the members,
>
> wherein said members are positioned in a spaced relationship relative to each other to reconfigure the chamber of the heart as at least two contiguous communicating portions of truncated ellipsoids.

Count 4:

> A static device for use with a heart having at least one chamber, said device comprising:

a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and

at least one connector for extending through the chamber joining the members together.

Count 5:

A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising:

a plurality of members configured to be positioned adjacent the epicardial surface of the heart, and

a connector for joining the members,

wherein said members are fixed in a spaced relationship relative to each other such that at least two discrete portions of the outer wall are displaced inwardly from the unrestricted position.

Count 6:

A method for reducing the wall tension on one of the chambers of the heart, comprising the steps of:

affixing a static brace external to the one chamber of the heart to reconfigure the chamber into at least two contiguous portions of truncated ellipsoids.

Count 7:

A device for reconfiguring a chamber of a natural heart, said device comprising:

a structure having a first and a second portion, said structure adapted to encircle the natural heart and to exert a constant inward displacement on at least two discrete portions of the exterior surface of one and only one chamber of the natural heart.

Proposed Count 3 incorporates the exact language of claim 40 of the present application and similar language of claim 1 of the '760 patent. Claim 1 of the '760

patent differs from claim 40 of this application in that claim 1 recites that "said device" (instead of "said members") is positioned in a spaced relationship relative to each other. Claim 1 is unclear since "each other" appears to refer back to the singular "device." Claim 1 of the '760 patent therefore may be indefinite under 35 U.S.C. § 112, second paragraph.

Proposed Counts 4, 5, and 6 incorporate the exact language of claims 41, 42, and 63 of the present application and claims 2, 3, and 28 of the '760 patent, respectively. Proposed Count 7 incorporates the exact language of claim 66 of the present application and substantially the same language of claim 36 of the '760 patent. Claim 36 of the '760 patent differs from claim 66 of the present application in that claim 66, while initially identical to claim 36 of the '760 patent, has now been amended to comply with 35 U.S.C. § 101, as required by the Examiner.

b. Claims Corresponding to the Proposed Counts

A claim should be designated as corresponding to the count if, considering the count as prior art, the claim would be unpatentable over the count under 35 U.S.C. § 102 or § 103. 37 C.F.R. § 41.207(b)(2).

In this case, assuming that Proposed Count 3 as recited above was prior art, claim 40 of this application and claim 1 of the '760 patent (assuming not indefinite under Section 112) would be unpatentable over Proposed Count 3 because these claims would be either anticipated by or rendered obvious by the subject matter of Proposed Count 3. For example, as shown in the claim chart in Section B(II)(b)(iii) below, claim 40 of the present application is identical to Proposed Count 3, and claim 1 of the '760

patent differs from Proposed Count 3 as described above. Therefore, claim 40 of this application and claim 1 of the '760 patent correspond to Proposed Count 3.

Assuming that Proposed Count 4 as recited above was prior art, claim 41 of this application and claim 2 of the '760 patent would be unpatentable over Proposed Count 4 because these claims would be anticipated by or rendered obvious by the subject matter of Proposed Count 4. For example, as shown in the claim chart in Section B(II)(b)(iii) below, claim 41 of the present application and claim 2 of the '760 patent are identical to Proposed Count 4. Therefore, claim 41 of this application and claim 2 of the '760 patent correspond to Proposed Count 4.

Assuming that Proposed Count 5 as recited above was prior art, claims 42-62 of this application and claims 3-27 and 32-35 of the '760 patent would be unpatentable over Proposed Count 5 because these claims would be either anticipated by or rendered obvious by the subject matter of Proposed Count 5. For example, as shown in the claim chart in Section B(II)(b)(iii) below, claim 42 of the present application and claim 3 of the '760 patent are identical to Proposed Count 5. Therefore, claims 42-62 of this application and claims 3-27 and 32-35 of the '760 patent correspond to Proposed Count 5.

Assuming that Proposed Count 6 as recited above was prior art, claims 63-65 of this application and claims 28-31 of the '760 patent would be unpatentable over Proposed Count 6 because these claims would be either anticipated by or rendered obvious by the subject matter of Proposed Count 6. For example, as shown in the claim chart in Section B(II)(b)(iii) below, claim 63 of the present application and claim 28 of the

'760 patent are identical to Proposed Count 6. Therefore, claims 63-65 of this application and claims 28-31 of the '760 patent correspond to Proposed Count 6.

Assuming that Proposed Count 7 as recited above was prior art, claims 66-79 of this application and claims 36-50 of the '760 patent would be unpatentable over Proposed Count 7 because these claims would be either anticipated by or rendered obvious by the subject matter of Proposed Count 7. For example, as shown in the claim chart in Section B(II)(b)(iii) below, claim 66 of the present application is identical to Proposed Count 7, and claim 36 of the '760 patent is substantially the same as Proposed Count 7. Therefore, claims 66-79 of this application and claims 36-50 of the '760 patent correspond to Proposed Count 7.

c. Claim Chart Comparing Interfering Subject Matter

37 C.F.R. § 41.202(a)(3) states: "For each count, provide a claim chart comparing at least one claim of each party corresponding to the count and show why the claims interfere within the meaning of § 41.203(a)."

As shown below, claim 40 of the present application is identical to Proposed Count 3, and claim 1 of the '760 patent is similar to Proposed Count 3. As explained above, claim 1 of the '760 patent differs from claim 40 of the present application (and Proposed Count 3) in its final clause. Specifically, claim 1 of the '760 patent differs from claim 40 of this application in that claim 1 recites that "said device" (instead of "said members") is positioned in a spaced relationship relative to each other. Accordingly, claim 40 of the present application and claim 1 of the '760 patent interfere within the meaning of § 41.203(a).

Proposed Count 3	Claim 40 of Present Application	Claim 1 of the '760 Patent
A static device for use with a heart having at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and a connector joining the members, wherein said members are positioned in a spaced relationship relative to each other to reconfigure the chamber of the heart as at least two contiguous communicating portions of truncated ellipsoids.	A static device for use with a heart having at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and a connector joining the members, wherein said members are positioned in a spaced relationship relative to each other to reconfigure the chamber of the heart as at least two contiguous communicating portions of truncated ellipsoids.	A static device for use with a heart having at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and a connector joining the members, wherein said device is positioned in a spaced relationship relative to each other to reconfigure the chamber of the heart as at least two contiguous communicating portions of truncated ellipsoids.

As shown below, claim 41 of the present application and claim 2 of the '760 patent are identical to Proposed Count 4, and therefore interfere within the meaning of § 41.203(a).

Proposed Count 4	Claim 41 of Present Application	Claim 2 of the '760 Patent
A static device for use with a heart having at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and at least one connector for	A static device for use with a heart having at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and at least one connector for	A static device for use with a heart having at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and at least one connector for

extending through the chamber joining the members together.	extending through the chamber joining the members together.	extending through the chamber joining the members together.

As shown below, claim 42 of the present application and claim 3 of the '760 patent are identical to Proposed Count 5, and therefore interfere within the meaning of § 41.203(a).

Proposed Count 5	**Claim 42 of Present Application**	**Claim 3 of the '760 Patent**
A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart, and a connector for joining the members, wherein said members are fixed in a spaced relationship relative to each other such that at least two discrete portions of the outer wall are displaced inwardly from the unrestricted position.	A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart, and a connector for joining the members, wherein said members are fixed in a spaced relationship relative to each other such that at least two discrete portions of the outer wall are displaced inwardly from the unrestricted position.	A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising: a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and a connector for joining the members; wherein said members are fixed in a spaced relationship relative to each other such that at least two discrete portions of the outer wall are displaced inwardly from the unrestricted position.

As shown below, claim 63 of the present application and claim 28 of the '760 patent are identical to Proposed Count 6, and therefore interfere within the meaning of § 41.203(a).

Proposed Count 6	Claim 63 of Present Application	Claim 28 of the '760 Patent
A method for reducing the wall tension on one of the chambers of the heart, comprising the steps of: affixing a static brace external to the one chamber of the heart to reconfigure the chamber into at least two contiguous portions of truncated ellipsoids.	A method for reducing the wall tension on one of the chambers of the heart, comprising the steps of: affixing a static brace external to the one chamber of the heart to reconfigure the chamber into at least two contiguous portions of truncated ellipsoids.	A method for reducing the wall tension on one of the chambers of the heart, comprising the steps of: affixing a static brace external to the one chamber of the heart to reconfigure the chamber into at least two contiguous portions of truncated ellipsoids.

As shown below, claim 66 of the present application is identical to Proposed Count 7, and claim 36 of the '760 patent is substantially the same as Proposed Count 7. Claim 66 of this application and claim 36 of the '760 patent therefore interfere within the meaning of § 41.203(a).

Proposed Count 7	Claim 66 of Present Application	Claim 36 of the '760 Patent
A device for reconfiguring a chamber of a natural heart, said device comprising: a structure having a first and a second portion, said structure adapted to encircle the natural heart and to exert a constant inward displacement on at least two discrete portions of the exterior surface of one and only one chamber of the natural heart.	A device for reconfiguring a chamber of a natural heart, said device comprising: a structure having a first and a second portion, said structure adapted to encircle the natural heart and to exert a constant inward displacement on at least two discrete portions of the exterior surface of one and only one chamber of the natural heart.	A device for reconfiguring a chamber of a natural heart, said device comprising: a structure having a first and a second portion, that encircles the natural heart and is adapted to exert a constant inward displacement on at least two discrete portions of the exterior surface of one and only one chamber of the natural heart.

d. Summary of Proposed Counts and Corresponding Claims

For the Examiner's ease of reference, Applicants include the following chart summarizing the Proposed Counts and corresponding claims. Should the Examiner wish to discuss the Counts and claims, or any other issue relating to this application and potential interference, he is invited to contact the undersigned at 202-408-4140.

Proposed Count	Corresponding Claims of this Application	Corresponding Claims of the '408 Patent	Corresponding Claims of the '760 Patent
1	15-33	1-24, 31-33, and 38-39	
2	34-39	34-37	
3	40		1
4	41		2
5	42-62		3-27 and 32-35
6	63-65		28-31
7	66-79		36-50

C. Explanation as to Why Applicants Will Prevail on Priority

As discussed in Section VI below, the entire disclosure of the present application derives from the January 2, 1997, filing of Application No. 08/778,277, which constitutes a constructive reduction to practice of the Proposed Counts. Accordingly, with respect to the Proposed Counts, Applicants are entitled to the benefit of the January 2, 1997, filing date of Application No. 08/778,277.

The '760 patent, which issued to Melvin from Application No. 09/598,424, was filed on June 21, 2000, and claims priority as a continuation of the '408 patent. The

'408 patent issued to Melvin from Application No. 09/035,710, filed on March 5, 1998. Assuming that Melvin can demonstrate that he is entitled to the benefit of the filing date of Application No. 09/035,710, the '408 and '760 patents' effective filing date for purposes of an interference is March 5, 1998. This is over fourteen months later than Applicants' January 2, 1997, constructive reduction to practice. Accordingly, Applicants are entitled to the benefit of an earlier effective filing date for the Proposed Counts, relative to the '408 and '760 patents.

Parties are presumed to have invented interfering subject matter in the order of the dates of their accorded benefit for each count. 37 C.F.R. § 41.207(a)(1). Accordingly, by virtue of being accorded benefit of an earlier filing date for the Proposed Counts, Applicants should be designated as the Senior Party, are presumed to have invented the interfering subject matter before Melvin, and do not have the burden of proving priority. Thus, Applicants expect to prevail in the interference on the basis of this presumption, or, if necessary, by proving a date of invention prior to January 2, 1997.

D. Claims Added or Amended to Provoke Interference

Claims 15-39 of the present application were added in the Preliminary Amendment of February 14, 2002, in order to provoke an interference. Similarly, claims 40-79 were added in the Amendment of January 24, 2003, in order to provoke an interference.

1. Claim Chart Showing Written Description Support for Claims 15-79 in the Present Application Specification

37 C.F.R. § 41.202(a)(5) requires an applicant to provide a claim chart showing the written description support in the applicant's specification for any claim that has

been added or amended to provoke an interference. A claim chart showing written description support for claims 15-79 in Applicants' specification is included as Exhibit C. The support provided is meant to be representative only. The specification provides additional support for claims 15-79. Nevertheless, as shown in Exhibit C, Applicants' present application provides full written description for claims 15-79 of the present application.

2. The Requirements of 35 U.S.C. § 135(b) are Satisfied

In compliance with 35 U.S.C. § 135(b), Applicants claimed the same or substantially the same subject matter as the claims of the '408 and '760 patents less than one year after each of those patents issued. In particular, Applicants added claims 15-39 to the present application by the Preliminary Amendment filed on February 14, 2002. This date is less than one year after the '408 patent issued on February 20, 2001. Additionally, Applicants added claims 40-79 to the present application by the Amendment filed on January 24, 2003. This date is less than one year after the '760 patent issued on June 25, 2002. Applicants have therefore satisfied the requirements of 35 U.S.C. § 135(b).

E. U.S. Patent Application No. 08/778,277 Provides a Constructive Reduction to Practice of the Proposed Counts

37 C.F.R. § 41.202(a)(6) requires an applicant, for each constructive reduction to practice for which the applicant wishes to be accorded benefit, to show where the disclosure provides a constructive reduction to practice within the scope of the interfering subject matter.

The present application is a continuation application of U.S. Patent Application No. 09/985,361, filed November 2, 2001, now U.S. Patent No. 6,589,160, which is a

continuation application of U.S. Patent Application No. 09/697,597, filed October 27, 2000, now U.S. Patent No. 6,332,864, which is a continuation of U.S. Patent Application No. 09/492,777, filed January 28, 2000, now U.S. Patent No. 6,162,168, which is a continuation of U.S. Patent Application No. 08/778,277 ("the '277 application"), filed January 2, 1997, now U.S. Patent No. 6,050,936. Each of these applications has a disclosure identical to the originally-filed disclosure of the '277 application. Accordingly, the '277 application constitutes a constructive reduction to practice of the Proposed Counts. A copy of the '277 application is attached as Exhibit D. The claim charts below show that Applicants describe all elements of the Proposed Counts in the '277 application.

Proposed Count 1	**Representative Support in '277 Application**
A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising:	"The present invention pertains to a non-pharmacological, passive apparatus for the treatment of a failing heart." (p. 4, ll. 22-23.) See also at least Figures 3 and 4, and the corresponding written description of those Figures.
a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and	"The clamp includes at least two ends having atraumatic anchoring member[s] disposed thereon for engagement with the heart or chamber wall." (p. 5, ll. 20-23) "Here a compression frame structure 300 is engaged with heart 14 at atraumatic anchor pads 310. A compression member 312 having an atraumatic surface 314 presses against a wall of left ventricle 10 to reduce the radius or cross-sectional area thereof." (p. 8, l. 26 - p. 9, l. 4.) "In this case a clamp 400 having atraumatic anchor pads 410 biased toward each other is shown disposed on a wall of left ventricle 10. (p. 9, ll. 7-9.) See also at least Figures 3 and 4, and the corresponding written description of those Figures.
a connector joining the members, and said	"In another embodiment of the apparatus, a frame is provided for supporting the compression member. Yet

connector comprises a band configured for extending around the chamber and joining at least two of the members, wherein said members are fixed in a spaced relationship relative to each other such that at least two portions of the outer wall are displaced inwardly from the unrestricted position.	another embodiment of the invention includes a clamp having two ends biased toward one another for drawing at least two walls of a heart chamber toward each other." (p. 5, ll. 15-20.) See also at least Figures 3 and 4, and the corresponding written description of those Figures.

Proposed Count 2	**Representative Support in '277 Application**
A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising:	"The present invention pertains to a non-pharmacological, passive apparatus for the treatment of a failing heart." (p. 4, ll. 22-23.) "In one embodiment, the apparatus includes a tension member for drawing at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane." (p. 5, ll. 6-9.) See also at least Figures 1, 5, and 6, and the corresponding written description of those Figures.
a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and	"The tension member has anchoring member[s] disposed at opposite ends for engagement with the heart or chamber wall." (p. 5, ll. 9-11.) "Extending through the left ventricle is a splint 16 including a tension member 18 and oppositely disposed anchors 20." (p. 8, ll. 5-7.) "Figures 10 and 11 are side views of a hinged anchor 28 which could be substituted for anchors 20 in undeployed and deployed positions respectively. Anchor 28 as shown in Figure 10 includes two legs similar to bar anchor 26. Hinged anchor 28 could include additional legs and the length of those legs could be varied to distribute the force over the surface of the heart wall." (p. 11, ll. 6-12.) "Figure 12 is a cross-sectional view of a capture ball anchor 30. Capture ball anchor 30 can be used in place of anchor 20. Capture ball anchor 30 includes a disk portion 32 to distribute the force of the anchor on the heart wall, and a recess 34 for receiving a ball 36 fixed to an end of the tension member 18." (p. 11, ll. 17-22.) "Figure

	13 is a perspective view of a cross bar anchor 40. The cross bar anchor 40 can be used in place of anchors 20." (p. 12, ll. 1-2.) See also at least Figures 1, 5, 6, and 10-13, and the corresponding written description of those Figures.
a first connector joining the members, the first connector having portions configured to be encased in the tissue of the heart, wherein said members are fixed in a spaced relationship relative to each other such that at least two portions of the outer wall are displaced inwardly from the unrestricted position.	"In one embodiment, the apparatus includes a tension member for drawing at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane. The tension member has anchoring member[s] disposed at opposite ends for engagement with the heart or chamber wall." (p. 5, ll. 6-11.) "Extending through the left ventricle is a splint 16 including a tension member 18 and oppositely disposed anchors 20. Splint 16 as shown in Figure 1 has been positioned to draw opposite walls of left ventricle 10 toward each other to reduce the 'radius' of the left ventricular cross-section or the cross-sectional area thereof to reduce left ventricular wall stresses." (p. 8, ll. 5-11.) "The embodiment 116 shown in Figure 5 includes three tension members 118 as opposed to a single tension member 18 as shown in Figure 1. Figure 6 shows yet another embodiment of the splint 216 having four tension members 218." (p. 9, ll. 19-23.) See also at least Figures 1, 5, and 6, and the corresponding written description of those Figures.

Proposed Count 3	**Representative Support in '277 Application**
A static device for use with a heart having at least one chamber, said device comprising:	"The present invention pertains to a non-pharmacological, passive apparatus for the treatment of a failing heart." (p. 4, ll. 22-23.) "In one embodiment, the apparatus includes a tension member for drawing at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane." (p. 5, ll. 6-9.) See also at least Figures 1, 3, 5, and 6, and the corresponding written description of those Figures.
a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and	"The tension member has anchoring member[s] disposed at opposite ends for engagement with the heart or chamber wall." (p. 5, ll. 9-11.) "Extending through the left ventricle is a splint 16 including a tension member 18 and

	oppositely disposed anchors 20." (p. 8, ll. 5-7.) "Here a compression frame structure 300 is engaged with heart 14 at atraumatic anchor pads 310. A compression member 312 having an atraumatic surface 314 presses against a wall of left ventricle 10 to reduce the radius or cross-sectional area thereof." (p. 8, l. 26 - p. 9, l. 4.) "Figures 10 and 11 are side views of a hinged anchor 28 which could be substituted for anchors 20 in undeployed and deployed positions respectively. Anchor 28 as shown in Figure 10 includes two legs similar to bar anchor 26. Hinged anchor 28 could include additional legs and the length of those legs could be varied to distribute the force over the surface of the heart wall." (p. 11, ll. 6-12.) "Figure 12 is a cross-sectional view of a capture ball anchor 30. Capture ball anchor 30 can be used in place of anchor 20. Capture ball anchor 30 includes a disk portion 32 to distribute the force of the anchor on the heart wall, and a recess 34 for receiving a ball 36 fixed to an end of the tension member 18." (p. 11, ll. 17-22.) "Figure 13 is a perspective view of a cross bar anchor 40. The cross bar anchor 40 can be used in place of anchors 20." (p. 12, ll. 1-2.) See also at least Figures 1, 3, 5, 6, and 10-13, and the corresponding written description of those Figures.
a connector joining the members, wherein said members are positioned in a spaced relationship relative to each other to reconfigure the chamber of the heart as at least two contiguous communicating portions of truncated ellipsoids.	"In one embodiment, the apparatus includes a tension member for drawing at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane. The tension member has anchoring member[s] disposed at opposite ends for engagement with the heart or chamber wall." (p. 5, ll. 6-11.) "Extending through the left ventricle is a splint 16 including a tension member 18 and oppositely disposed anchors 20." (p. 8, ll. 5-7.) "Here a compression frame structure 300 is engaged with heart 14 at atraumatic anchor pads 310." (p. 8, l. 26 - p. 9, l. 1.) "Figure 15 is a view of the idealized heart chamber 48 of Figure 14 wherein the chamber has been splinted along its length L such that a 'figure eight' cross-section has been formed along the length thereof." (p. 13, ll. 1-4.) See also at least Figures 1, 3, 5, 6, and 15-18, and the corresponding written description of those Figures.

Proposed Count 4	Representative Support in '277 Application
A static device for use with a heart having at least one chamber, said device comprising:	"The present invention pertains to a non-pharmacological, passive apparatus for the treatment of a failing heart." (p. 4, ll. 22-23.) "In one embodiment, the apparatus includes a tension member for drawing at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane." (p. 5, ll. 6-9.) See also at least Figures 1, 5, and 6, and the corresponding written description of those Figures.
a plurality of members configured to be positioned adjacent the epicardial surface of the heart; and	"The tension member has anchoring member[s] disposed at opposite ends for engagement with the heart or chamber wall." (p. 5, ll. 9-11.) "Extending through the left ventricle is a splint 16 including a tension member 18 and oppositely disposed anchors 20." (p. 8, ll. 5-7.) "Figures 10 and 11 are side views of a hinged anchor 28 which could be substituted for anchors 20 in undeployed and deployed positions respectively. Anchor 28 as shown in Figure 10 includes two legs similar to bar anchor 26. Hinged anchor 28 could include additional legs and the length of those legs could be varied to distribute the force over the surface of the heart wall." (p. 11, ll. 6-12.) "Figure 12 is a cross-sectional view of a capture ball anchor 30. Capture ball anchor 30 can be used in place of anchor 20. Capture ball anchor 30 includes a disk portion 32 to distribute the force of the anchor on the heart wall, and a recess 34 for receiving a ball 36 fixed to an end of the tension member 18." (p. 11, ll. 17-22.) "Figure 13 is a perspective view of a cross bar anchor 40. The cross bar anchor 40 can be used in place of anchors 20." (p. 12, ll. 1-2.) See also at least Figures 1, 5, 6, and 10-13, and the corresponding written description of those Figures.
at least one connector for extending through the chamber joining the members together.	"Extending through the left ventricle is a splint 16 including a tension member 18 and oppositely disposed anchors 20." (p. 8, ll. 5-7.) "The embodiment 116 shown in Figure 5 includes three tension members 118 as opposed to a single tension member 18 as shown in Figure 1. Figure 6 shows yet another embodiment of the splint 216 having four tension members 218." (p. 9, ll. 19-23.) See also at least Figures 1, 5, and 6, and the corresponding written description of those Figures.

Proposed Count 5	Representative Support in '277 Application
A static device for use with an unrestricted heart having an outer wall and at least one chamber, said device comprising:	"The present invention pertains to a non-pharmacological, passive apparatus for the treatment of a failing heart." (p. 4, ll. 22-23.) "In one embodiment, the apparatus includes a tension member for drawing at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane." (p. 5, ll. 6-9.) See also at least Figures 1 and 3-6, and the corresponding written description of those Figures.
a plurality of members configured to be positioned adjacent the epicardial surface of the heart, and	"The tension member has anchoring member[s] disposed at opposite ends for engagement with the heart or chamber wall." (p. 5, ll. 9-11.) "The clamp includes at least two ends having atraumatic anchoring member[s] disposed thereon for engagement with the heart or chamber wall." (p. 5, ll. 20-23) "Extending through the left ventricle is a splint 16 including a tension member 18 and oppositely disposed anchors 20." (p. 8, ll. 5-7.) "Here a compression frame structure 300 is engaged with heart 14 at atraumatic anchor pads 310. A compression member 312 having an atraumatic surface 314 presses against a wall of left ventricle 10 to reduce the radius or cross-sectional area thereof." (p. 8, l. 26 - p. 9, l. 4.) "In this case a clamp 400 having atraumatic anchor pads 410 biased toward each other is shown disposed on a wall of left ventricle 10. (p. 9, ll. 7-9.) "Figures 10 and 11 are side views of a hinged anchor 28 which could be substituted for anchors 20 in undeployed and deployed positions respectively. Anchor 28 as shown in Figure 10 includes two legs similar to bar anchor 26. Hinged anchor 28 could include additional legs and the length of those legs could be varied to distribute the force over the surface of the heart wall." (p. 11, ll. 6-12.) "Figure 12 is a cross-sectional view of a capture ball anchor 30. Capture ball anchor 30 can be used in place of anchor 20. Capture ball anchor 30 includes a disk portion 32 to distribute the force of the anchor on the heart wall, and a recess 34 for receiving a ball 36 fixed to an end of the tension member 18." (p. 11, ll. 17-22.) "Figure 13 is a perspective view of a cross bar anchor 40. The cross bar anchor 40 can be used in place of anchors 20." (p. 12, ll. 1-2.) See also at least Figures 1, 3-6, and 10-13, and the corresponding written description of those Figures.
a connector for joining the	"In one embodiment, the apparatus includes a tension

members, wherein said members are fixed in a spaced relationship relative to each other such that at least two discrete portions of the outer wall are displaced inwardly from the unrestricted position.	member for drawing at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane. The tension member has anchoring member[s] disposed at opposite ends for engagement with the heart or chamber wall." (p. 5, ll. 6-11.) "In another embodiment, the apparatus includes a compression member for drawing at least two walls of a heart chamber toward each other." (p. 5, ll. 12-14.) "Yet another embodiment of the invention includes a clamp having two ends biased toward one another for drawing at least two walls of a heart chamber toward each other. The clamp includes at least two ends having atraumatic anchoring member[s] disposed thereon for engagement with the heart or chamber wall." (p. 5, ll. 18-23.) "Extending through the left ventricle is a splint 16 including a tension member 18 and oppositely disposed anchors 20. Splint 16 as shown in Figure 1 has been positioned to draw opposite walls of left ventricle 10 toward each other to reduce the 'radius' of the left ventricular cross-section or the cross-sectional area thereof to reduce left ventricular wall stresses." (p. 8, ll. 5-11.) "Figure 3 shows yet another alternative embodiment of the present invention deployed with respect to left ventricle 10 of human heart 14. Here a compression frame structure 300 is engaged with heart 14 at atraumatic anchor pads 310. A compression member 312 having an atraumatic surface 314 presses against a wall of left ventricle 10 to reduce the radius or cross-sectional area thereof. Figure 4 is a transverse cross-sectional view of human heart 14 showing yet another embodiment of the present invention. In this case a clamp 400 having atraumatic anchor pads 410 biased toward each other is shown disposed on a wall of left ventricle 10. (p. 8, l. 24 - p. 9, l. 9.) "It is anticipated that in some patients, the disease process of the failing heart may be so advanced that three, four or more tension members may be desirable to reduce the heart wall stresses more substantially than possible with a single tension member as shown in Figure 1." (p. 9, l. 23 - p. 10, l. 2.) See also at least Figures 1 and 3-6, and the corresponding written description of those Figures.

Proposed Count 6	**Representative Support in '277 Application**
A method for reducing the wall tension on one of the	"The present invention pertains to a non-pharmacological, passive apparatus for the treatment of a failing heart. The

chambers of the heart, comprising the steps of:	device is configured to reduce the tension in the heart wall." (p. 4, ll. 22-24.) "The device reduces wall tension during diastole (preload) and systole." (p. 5, ll. 4-5.) "Splint 16 as shown in Figure 1 has been positioned to draw opposite walls of left ventricle 10 toward each other to reduce the 'radius' of the left ventricular cross-section or the cross-sectional area thereof to reduce left ventricular wall stresses." (p. 8, ll. 7-11.) "It is anticipated that in some patients, the disease process of the failing heart may be so advanced that three, four or more tension members may be desirable to reduce the heart wall stresses more substantially than possible with a single tension member as shown in Figure 1." (p. 9, l. 23 - p. 10, l. 2.)
affixing a static brace external to the one chamber of the heart to reconfigure the chamber into at least two contiguous portions of truncated ellipsoids.	"In one embodiment, the apparatus includes a tension member for drawing at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane." (p. 5, ll. 6-9.) "In another embodiment, the apparatus includes a compression member for drawing at least two walls of a heart chamber toward each other." (p. 5, ll. 12-14.) "Yet another embodiment of the invention includes a clamp having two ends biased toward one another for drawing at least two walls of a heart chamber toward each other." (p. 5, ll. 18-20.) "Extending through the left ventricle is a splint 16 including a tension member 18 and oppositely disposed anchors 20. Splint 16 as shown in Figure 1 has been positioned to draw opposite walls of left ventricle 10 toward each other to reduce the 'radius' of the left ventricular cross-section or the cross-sectional area thereof to reduce left ventricular wall stresses." (p. 8, ll. 5-11.) "Figure 2 discloses an alternate embodiment of the present invention, wherein a balloon 200 is deployed adjacent the left ventricle." (p. 8, ll. 19-21.) "Figure 3 shows yet another alternative embodiment of the present invention deployed with respect to left ventricle 10 of human heart 14. Here a compression frame structure 300 is engaged with heart 14 at atraumatic anchor pads 310. A compression member 312 having an atraumatic surface 314 presses against a wall of left ventricle 10 to reduce the radius or cross-sectional area thereof." (p. 8, l. 24 - p. 9, l. 4.) "As a consequence of placing splint 16, the radius or cross-sectional area of the left ventricle affected by the scar tissue 24 is reduced. The reduction of this radius or

	cross-sectional area results in reduction in the wall stress in the left ventricular wall and thus improves heart pumping efficiency." (p. 10, ll. 15-20.) "Figure 15 is a view of the idealized heart chamber 48 of Figure 14 wherein the chamber has been splinted along its length L such that a 'figure eight' cross-section has been formed along the length thereof." (p. 13, ll. 1-4.) See also at least Figures 1-3, 5, 6, 8, and 15-18, and the corresponding written description of those Figures.

Proposed Count 7	**Representative Support in '277 Application**
A device for reconfiguring a chamber of a natural heart, said device comprising:	"The present invention pertains to a non-pharmacological, passive apparatus for the treatment of a failing heart." (p. 4, ll. 22-23.) See also at least Figures 3 and 4, and the corresponding written description of those Figures.
a structure having a first and a second portion, said structure adapted to encircle the natural heart and to exert a constant inward displacement on at least two discrete portions of the exterior surface of one and only one chamber of the natural heart.	"In another embodiment, the apparatus includes a compression member for drawing at least two walls of the heart chamber toward each other." (p. 5, ll. 12-14.) "Yet another embodiment of the invention includes a clamp having two ends biased toward one another for drawing at least two walls of a heart chamber toward each other. The clamp includes at least two ends having atraumatic anchoring member[s] disposed thereon for engagement with the heart or chamber wall." (p. 5, ll. 18-23.) "Here a compression frame structure 300 is engaged with heart 14 at atraumatic anchor pads 310. A compression member 312 having an atraumatic surface 314 presses against a wall of left ventricle 10 to reduce the radius or cross-sectional area thereof." (p. 8, l. 26 - p. 9, l. 4.) "In this case a clamp 400 having atraumatic anchor pads 410 biased toward each other is shown disposed on a wall of left ventricle 10." (p. 9, ll. 7-9.) See also at least Figures 3 and 4, and the corresponding written description of those Figures.

The claim charts above demonstrate that the parent application, i.e., the '277 application, provides a constructive reduction to practice for the Proposed Counts. Therefore, Applicants are entitled, for interference purposes, to the January 2, 1997, filing date of the parent application.

III. Conclusion

Applicants respectfully request that an interference be declared between the present application and the '408 and '760 patents. In declaring the interference, the Patent Office is requested to define the counts as the Proposed Counts set forth above and to designate claims 15-79 of this application and claims 1-24 and 31-39 of the '408 patent and claims 1-50 of the '760 patent to correspond to the Proposed Counts. Applicants have demonstrated their right to a constructive reduction to practice as of January 2, 1997, which is earlier than the patentee's earliest possible effective filing date of March 5, 1998. Accordingly, Applicants request that they be designated as Senior Party in the interference.

If any fees are due in connection with the filing of this Response and Suggestion for Interference that are not otherwise provided, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: January 23, 2006

By: _____
Leslie I. Bookoff
Reg. No. 38,084

Attachments:

Exhibit A - Copy of U.S. Patent No. 6,190,408
Exhibit B - Copy of U.S. Patent No. 6,409,760
Exhibit C - Representative Written Description Support in in Present Specification for Claims 15-79
Exhibit D - Copy of originally-filed application and drawings for Application Serial No. 08/778,277